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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,707	08/16/2006	Edgar Zimmer	5305-14PUS	8798

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EXAMINER
GIONTA, ALLISON

ART UNIT	PAPER NUMBER
1777	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,707	ZIMMER, EDGAR	
	Examiner	Art Unit	
	ALLISON GIONTA	1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-38 are canceled. Claims 39-53 are withdrawn. Claims 54-74 are rejected.

35 USC § 112, Sixth Paragraph

Claims 54 and 55 invoke 35 USC 112, sixth paragraph. Claims 54 and 55 recite "an adjusting means for adjusting the ratio of the wash fluid and the permeate stream that are fed to the product stream". In paragraph 0044 of the instant application's PG Pub applicant defines this means for as "an automatic control system which, if necessary, can carry out a control action as a function of the measured flow amounts according to specific predetermined criteria…" There is no further structural definition of the "automatic control system".

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 54-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipnizki et al. (Lipnizki et al., Concepts of industrial-scale diafiltration systems, Desalination, 144, 2002, 179-184) and further in view of Martin et al. (5958245).

Regarding claims 54, 55, 56, 57, 58, 59, 63, 67, 68, 69, 70 and 74, Lipnizki et al. teach a device for carrying out the diafiltration of a product (abstract), the device comprising a membrane filtration means with a product inlet, a product outlet and a permeate outlet, a product supply line for feeding a product stream to the product inlet of the membrane filtration means, a wash fluid supply line for feeding a wash fluid stream to the product stream, a permeate supply line for feeding a permeate stream derived from the product itself to the product stream and an adjusting means for adjusting the ratio of the wash fluid stream and the permeate stream that are fed to the product stream. The permeate supply line is designed as a permeate return line for returning permeate from the permeate outlet of the membrane filtration means to the product stream (See Figure 1.3 reproduced below and annotated, Filter 5). A product feed line and discharge line are also pictured below. The product feed line opens into the product circulation upstream of the product discharge line (see also below). The wash fluid supply line and the permeate supply line open into the product stream by two separate openings (See below). In the embodiment shown on page 183, Figure 2 (1), a wash pump is installed in the wash fluid supply line (pg. 183, Fig. 2 (1)). Lipnizki et al.'s system is a multistage, closed loop system (see below).

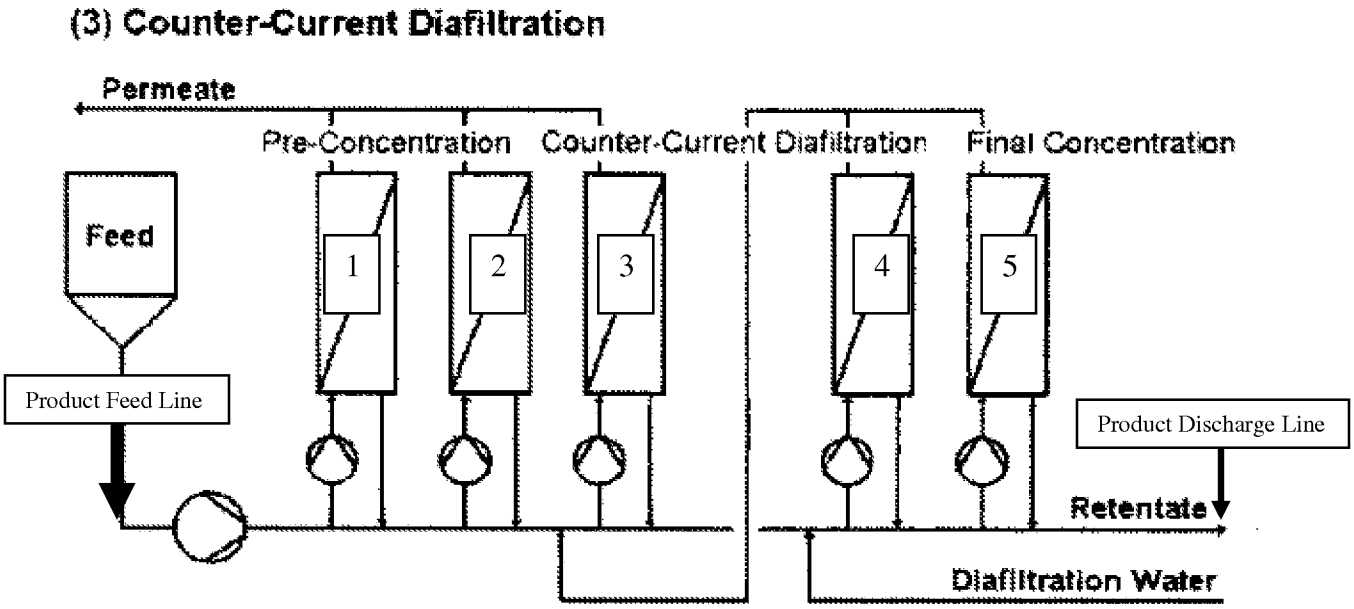
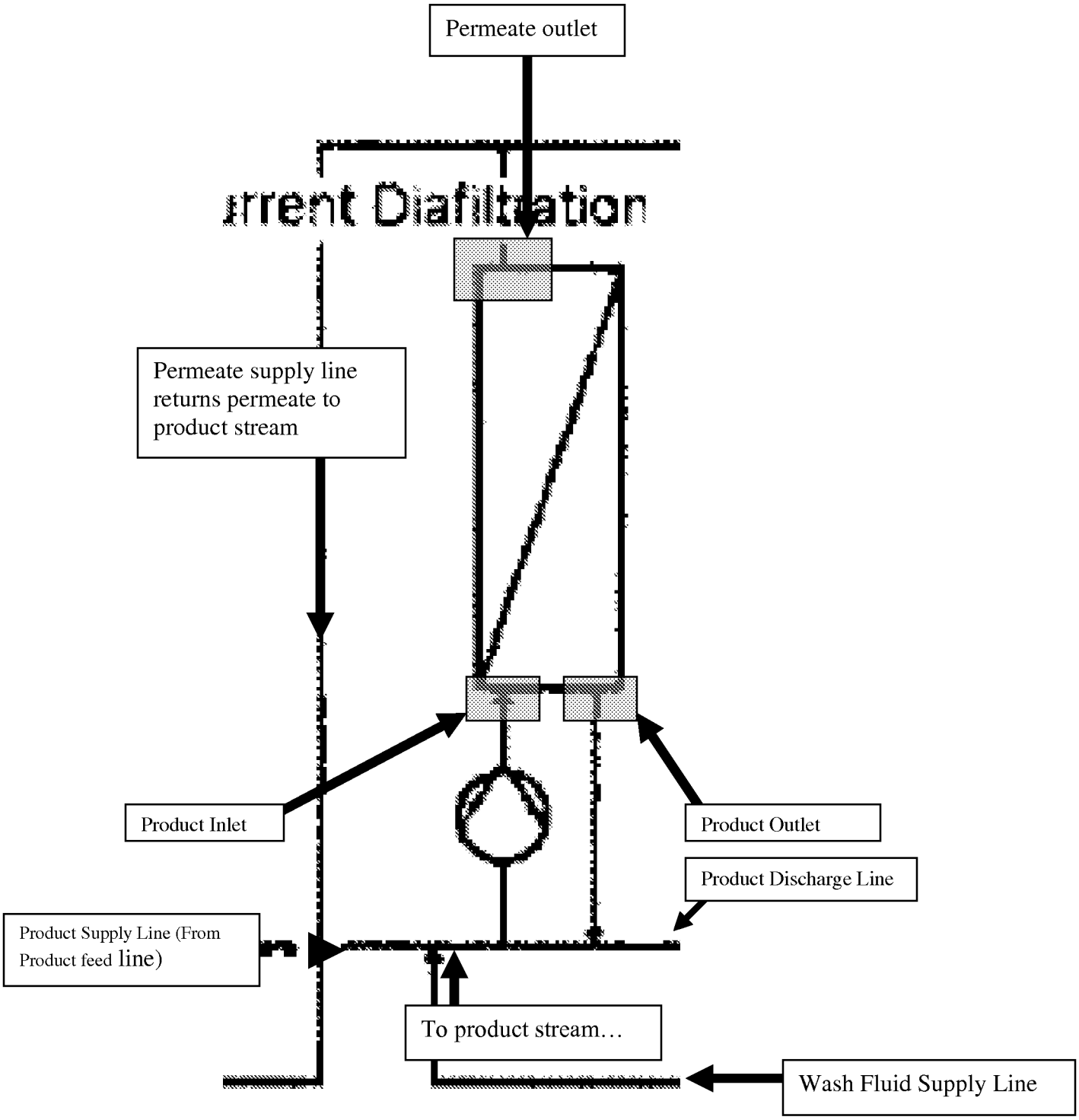


Fig. 1. Concepts of diafiltration.

For details of the return lines, inlets, outlets etc. please see the enlarged view of filter (4) produced below.


Permeate outlet
Permeate supply line returns permeate to product stream
Product Inlet
Product Outlet
Product Discharge Line
Product Supply Line (From Product feed line)
To product stream…
Wash Fluid Supply Line

Lipnikzki et al. further teach that the filtration device may be used in filtration plants (Pg. 180, **Introduction;** pg. 181, col. 1, 2nd paragraph).

Clearly, from the figured reproduced above, it is clear that the filtration plant comprising the dialfiltration device may comprise one or more additional diafiltration stages installed upstream of the device (Figure 1.3, Filter 4) wherein the diafiltration stages can be supplied with permeate of the next downstream filtration stage (see permeate recycle stream from filter 5 to upstream of filter 4).

Lipnizki et al. also teach that a pre-concentration step for achieving particular concentrations of low molecular weight components in retentate and permeate is completed prior to the diafiltration step (pg. 180, **Introduction**). They further teach that ultrafiltration is well-known as a state of the art way to accomplish the concentration (**Introduction**). Therefore, an ultrafiltration stage is provided upstream of the diafiltration stage.

Lipnizki et al. do not teach specifically that the pump connects the product inlet and the product outlet. However, as Lipnizki et al. show and as would be appreciated by anyone of ordinary skill in the art at the time of the invention, pumps are well-known for use in circulating fluid. Anyone of ordinary skill in the art at the time of the invention would have been motivated to provide a pump between the product inlet and the product outlet as to pump the feed coming in through the system. For instance, incorporating a pump in the feed line between the product inlet line and the product outlet line would help circulate the feed and connect the inlet and the outlet.

Further, the claims are drawn to an apparatus. The manner of operating an apparatus does not distinguish it over the prior art. The structure must be sufficiently recited to overcome the prior art.

Lipnizki et al. do not teach that the diafiltration device comprises an adjusting means for adjusting the volumetric ratio between the wash fluid and the permeate stream to control a viscosity of the permeate stream, wherein the adjusting means can adjust the wash fluid and the permeate streams independently of each other, and can adjust the ratio of the amount of wash fluid supplied to the permeate can be automatically adjusted in a closed-loop control system or wherein the adjusting means can automatically adjust the amount of permeate fed to the individual stages.

However, in the analogous art of diafiltration, Martin et al. teach that it is well-known and extremely obviously to incorporate an automatic control system such as a computer (col. 6, lines 45-55). Martin et al.'s computer calculates the amount of washing fluid that should be added and controls the influx of the washing fluid (col. 6, lines 46-49). Therefore, their computer is an automatic control or adjusting means which adjusts the ratio of the wash fluid supplied to the permeate. While Martin et al. do not teach that the computer adjusts the permeate stream or wherein it can adjust the permeate stream and the wash stream independently of each other, the computer described by Marin et al. is capable of being programmed in a way which would enable the computer to control the retentate and the wash stream independently.

Lipnizki et al. teach that minimizing wash fluid (diafiltration water) and minimizing equipment requirements is of concern when contemplating diafiltration (abstract; pg. 181, col. 1-2, para. 2). Martin et al. provide a way for automating Lipnizki et al.'s device which would

reduce wash waste (using calculated measurements, removing human error) and would reduce the requirements for equipment space. Further, automation reduces the number of employees required to maintain a diafiltration plant.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to automate Lipnizki et al.'s device for the benefit of cutting production costs, minimizing waste and reducing the space required for equipment.

Further, the examiner would like to remind applicant that providing a mechanical or automatic means to replace manual activity, which accomplishes the same result, is within the ambit of a person of ordinary skill in the art. See In re Venner, 120 USPQ 192 (CCPA 1958) (see MPEP § 2144.04).

Regarding claims 60, 61 and 62, the prior art remains as applied to claim 59 above. While Lipnizki et al. teach a product feed line, product discharge line, product outlet, circulation pump, wash fluid line and permeate supply line, they do not teach the exact configuration of the wash fluid line, product feed line and product discharge line as claimed in claims 50-62.

However, the configurations are extremely similar (see the figures provided above). In fact, at some point each "line" passes between the product outlet and the circulation pump, as is claimed. Further, the Courts have held that the mere rearrangement of parts, without any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See In re Japikse, 86 USPQ 70 (CCPA 1950) (see MPEP § 2144.04).

For further evidence that varying the configurations is well-known and within the ambit of one of ordinary skill in the art attention is drawn to Martin et al., Fig. 1 a similar configuration is depicted.

Regarding claims 64, 71 and 72, the prior art remains as applied to claims 62 and 68 above. The limitations of claims 64, 71 and 72 are construed as functional limitations of the system design. They do not reasonably convey any further structural limitations of the diafiltration system. Instead, they describe what the particular filtration system design does. The recited structure has been rendered obvious by Lipnizki et al. in view of Martin et al., as applied above. Because the "design" of the diafiltration system is fully taught, the functional limitations are inherent. Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. Further, the Courts have held that it is well settled that where there is a reason to believe that a functional characteristic would be inherent in the prior art, the burden of proof then shifts to the applicant to provide objective evidence to the contrary. See In re Schreiber, 128 F.3d at 1478, 44 USPQ2d at 1478, 44 USPQ2d at 1432 (Fed. Cir. 1997) (see MPEP § 2112.01, I.).

Regarding claim 65, 66 and 73, the prior art remains as applied to claims 64 and 72 above. Lipnizki et al. teach that pumps are well-known for their use in counter-current diafiltration (Table 3, see footnote) and are well-known to move liquid through the system. In one embodiment, Lipnizki et al. teach that pumps are commonly included in the wash fluid supply line (Pg. 183, Fig. 2.2 and 2.3). Lipnizki et al. do not explicitly state that a pump is provided in the permeate return line.

However, one of ordinary skill in the art at the time of the invention would have found it quite obvious to incorporate a pump in the return line of the diafiltration system for the benefit of moving the permeate through the closed-loop system.

Response to Arguments

4. Applicant's arguments filed 1/18/2011 have been fully considered but they are not persuasive.

Applicant argues:

1. Martin does not disclose an adjusting means that adjusts a volumetric ratio between the wash fluid stream and the permeate stream.

However, Martin does teach this as is seen in column 6, lines 45-55 of Martin:

> the volume of solution to be treated. Obviously, the quantity of water added for dilution can be calculated by a computer, not depicted, the water inlet being controlled by this computer. The diluted solution is then sent by means of a pump **5** and valves **9,9'** to the first nanofiltration membrane **2**. After passing through the first nanofiltration membrane **2**, the retentate is recirculated into the tank containing the fixing bath **1** as before, and the permeate is sent to a storage tank **8**. It is then directed to the second nanofiltration membrane **3** by means of the pump **5** and valves **9,9'**. The permeate

Further, Applicant argues that Figure 1 is the only embodiment which a wash fluid stream and a permeate stream can be fed simultaneously to the product to be filtered and that no computer is disclosed as controlling this embodiment. However, the Examiner submits that in column 6, lines 45-55, the water inlet of Figure 1 is described as being controlled by a computer (i.e. adjusting means) that is not pictured (see the excerpt above).

2. Applicant argues that even if the water inlet of Martin could be controlled, controlling Martin's inlet would not cause a change in the volumetric ratio of the was fluid stream and permeate stream because Martin teaches a system in which the permeate stream would increate or decree to the same degree or extent as the wash fluid and thus the ratio does not change.

The Examiner does not see the grounds on which applicant bases this argument. Martin teaches an automatic adjusting means that comprises a computer that calculates the amount of water to be added for dilution and then an adjusting means that controls the water inlet based on that calculation. Therefore, the water (diluent) amount is changing, which changes the volumetric ratio of water (diluent) to permeate.

3. Applicant lastly argues that there is no circulation pump that connects the product inlet to the product outlet in Lipnizki et al.'s system.

This argument is moot over grounds of new rejection provided above.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON GIONTA whose telephone number is (571)270-1767. The examiner can normally be reached on M-F: 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1777

/AMG/